PUBLIC HEALTH AND THE LAW

Immunization Programs: Further Legal Developments

William J. Curran, LL.M., S.M.Hyg.

LAST month in this column we discussed the very important case of *Davis v. Wyeth Laboratories, Inc.*,[1] involving drug company liability for paralysis allegedly resulting from Sabin Polio Vaccine Type III, administered in a mass immunization program. This month we are reporting on a case of perhaps equal importance involving drug company liability for injuries allegedly resulting from a single-dose administration of Quadrigen, the Parke-Davis and Co., product containing four antigens: diphtheria toxoid, tetanus toxoid, pertussis vaccine, and poliomyelitis vaccine. The case is *Tinnerholm v. Parke-Davis and Co.*,[2] decided by the United States District Court for the Southern District of New York.

The injection was administered to the infant plaintiff at the age of two months by the family physician. It was given on a Saturday. No immediate side effects were observed. On the following Tuesday, however, the child developed a fever of 108° and was hospitalized. On examination at the hospital the child was pale, with rapid breathing, eyes dull and apathetic, exhibiting focal seizures and twitching on the right side. The child developed recurrent seizures and on the fifth day a flaccid paralysis of the right arm and leg was observed. The child is now unable to walk or talk and is incapable of toilet training. He is mentally retarded "in the imbecile-idiot range," according to the opinion.

The case was hotly contested at trial. The court, in a long and very detailed opinion, found for the plaintiff and awarded damages of $651,783.52. The breakdown of the verdict is as follows:

I. For the plaintiff Carl F. Tinnerholm [father]	
(a) Reimbursement for medical expenses paid	$ 6,283.52
(b) For past medical expenses for which liable	33,000.00
(c) Loss of services	2,500.00
II. For the infant plaintiff Eric Tinnerholm	
(a) Future medical expenses	160,000.00
(b) Loss of future earnings	50,000.00
(c) Pain and suffering	400,000.00

The court found as a basis of liability that the defendant drug manufacturer had breached its implied warranty of fitness in that the product was defective for its intended use. The court also found Parke-Davis and Co., negligent in its failure adequately to test the product before it was marketed and for its failure adequately to warn the medical profession of the dangers inherent in its use. The particular cause of the injuries was found to be the unstable pertussis vaccine. The Court said,

> It is reasonable to conclude, as I do, with reasonable medical certainty or probability that the release of the endotoxin into the fluid injected into the infant plaintiff was the cause of the unusually high fever which, in turn, caused the severe and permanent brain damage. I find defendant's suggestion that the cause of such damage was a viral encephalitis caused by some unspecified virus, or a sepsis or meningitis, or an allergic reaction, totally unconvincing. . . . Plaintiffs' experts have furnished impressive evidence to support the conclusions reached herein, evidence which has clearly withstood the attack of defendant's experts.

In a key portion of the opinion, Judge Tenney asserts,

> It appears clear to this Court that Parke-Davis in its rush to commercialization of its product either overlooked or neglected to consider the possibility that Quadrigen was too unstable a vaccine and therefore too unpredictable to be released on the market at that time.

There is considerable criticism in the opinion of the clinical tests conducted by the company. The company's records and certain published papers regarding Quadrigen are used by the Court in arriving at these conclusions.

It should be noted that this is a trial-level decision. It will probably be appealed to the Federal Court of Appeals. A similar case has also been tried in a western state, but the decision and opinion have not as yet been handed down.

This decision, like the *Davis* case, has been a cause of concern not only to the drug manufacturers, but to public health authorities throughout the United States. It is feared that heavy verdicts in personal injury cases where satisfactory proof, like the *Davis* case (and more particularly *disproof*) of causal relation is difficult to obtain will discourage private drug concerns from entering certain preventive medicine-immunization fields. The defense in these cases is admittedly difficult. Federal government officials or scientists, often key figures in the defense case, are frequently available only through deposition (written statements), and not as live, courtroom witnesses. Depositions are rarely as effective as courtroom testimony for a variety of reasons. It is also said that sympathies will tend to lie with the injured plaintiff rather than with the large drug concerns and casualty insurance companies.

There are no simple answers to these problems. Strong legal arguments have been made to sustain these legal decisions. Also, juries are not always unduly sympathetic to injured plaintiffs. It should be recalled that in the *Davis* case reported upon last month, the District Court jury found for the defendant and denied damages to the paralyzed adult plaintiff. It was the appellate court which reversed the case and returned it for a new jury trial which has not yet been held. Until the *Tinnerholm* case and its companion case are decided upon appeal we cannot be sure of the legal trend of this field. It can be expected that the issues will be presented well on both sides. Some of the finest legal talent in the personal injury field will be involved in the making of new law of great importance to all public health people in the United States. We will be watching these developments in this column in the months ahead.

Dr. Curran is Frances Glessner Lee Professor of Legal Medicine on the faculties of Public Health and Medicine, Harvard University (55 Shattuck Street), Boston, Mass. 02115